



# IMS Health v. Sorrell – Implications for Federal Regulation of Pharmaceutical Marketing?

## Citation

Katherine Sullivan, IMS Health v. Sorrell – Implications for Federal Regulation of Pharmaceutical Marketing? (2011).

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*IMS Health v. Sorrell* – Implications for Federal Regulation of Pharmaceutical Marketing?  
Katherine M. Sullivan<sup>1</sup>

**ABSTRACT** In an era of increased scrutiny of laws regulating corporate speech, state and federal regulators must balance regulation of the prescription drug market with the budgetary and public health needs. One area of contention is the use of prescriber data for pharmaceutical marketing. Claiming a need to protect physician privacy and the state budget, Vermont limited access to this data. Pharmaceutical companies and data processors filed suit, claiming a violation of their First Amendment rights. The Supreme Court recently heard the case. The outcome could have broad implications not only for states' ability to protect privacy but also for FDA's restrictions on pharmaceutical marketing. If the Supreme Court chooses to invalidate Vermont's law, FDA's regulation of off-label promotion could be ripe for a judicial challenge.

I. Introduction

Getting a prescription filled by a local pharmacy appears to be a relatively straightforward endeavor. But behind a simple consumer transaction lurks a multi-million dollar industry.<sup>2</sup> Pharmacies routinely sell their prescription records to third parties, not in order to look at what patients are using,<sup>3</sup> but instead to help pharmaceutical companies tailor their marketing pitches to the practitioners who are doing the prescribing.<sup>4</sup> These pitches, carried out by pharmaceutical sales representatives known as “detailers,” have been increasing in volume and

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<sup>1</sup> J.D., Boston University School of Law, 2010; M.P.H., Harvard School of Public Health, 2011.

<sup>2</sup> For example, IMS Health, the industry leader, reported total 2009 revenues of \$2.2 billion. *See* IMS 2009 10-K at 59.

<sup>3</sup> See, e.g. Natasha Singer, Data Privacy Put to the Test, *New York Times*, May 1, 2011 at BU03. But see Paul Ohm, Broken Promises of Privacy: Responding to the Surprising Failures of Anonymization, 57 *UCLA L. Rev.* 1701 (2010) (examining whether “de-anonymized data is truly private”), and Brief of Amici Curiae Electronic Privacy Information Center and Legal Scholars and Technical Experts in Support of Petitioners, *IMS Health, Inc. v. Sorrell*, No. 10-779, March 1, 2011.

<sup>4</sup> See Pew Prescription Project, Prescription Data Mining Fact Sheet, Nov. 19, 2008, [http://www.prescriptionproject.org/tools/initiatives\\_factsheets/files/0004.pdf](http://www.prescriptionproject.org/tools/initiatives_factsheets/files/0004.pdf).

intensity over the past decade as pharmaceutical companies focus their resources on promoting the usage of approved drugs.<sup>5</sup>

In 2007, in response to the perceived threat to prescribers' privacy and financial concerns about the overutilization of brand name drugs instead of generic alternatives, Vermont passed Act 80, which attempts to limit access to physician prescribing histories held by pharmacies. PhRMA, the pharmaceutical industry association,<sup>6</sup> and data mining companies challenged the legislation on First Amendment grounds. The litigation is currently before the Supreme Court.<sup>7</sup>

The outcome of this case has important implications not only for states seeking to stop this practice but also for federal regulation of commercial speech. It also has deeper implications for the meaning of what interests the First Amendment is supposed to protect. This paper will analyze whether outcome of the Vermont litigation, *Sorrell v. IMS Health, Inc.*, will impact FDA's regulation of speech by pharmaceutical companies regarding off-label uses for their products. To demonstrate the threat posed by *IMS Health* to FDA's off-label prohibitions, I will first discuss commercial speech doctrine relevant to the dispute. Next, I will explain FDA's regulation of off-label promotion, and the problems that FDA already faces vis a vis the commercial speech cases. Next, I will examine the *IMS Health* litigation in depth. Finally, in light of the recent Supreme Court oral argument, I will conclude with an evaluate potential outcomes of *IMS Health* and their capacity to impact FDA regulation of the pharmaceutical industry.

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<sup>5</sup> See Sheryl Gay Stolberg & Jeff Garth, High-Tech Stealth Being Used To Sway Doctor Prescriptions, N.Y. Times, Nov. 16, 2000; see also *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434, 442 (D. Vt. 2009).

<sup>6</sup> About PhRMA, <http://www.phrma.org/about/phrma>, last visited May 5, 2011.

<sup>7</sup> See *Sorrell v. IMS Health, Inc.*, No 10-779.

## II. Commercial Speech and the First Amendment

This section will briefly outline the Supreme Court's evolving approach to First Amendment protections for commercial speech. For both FDA and the State of Vermont, the First Amendment question is whether government can limit corporations' ability to make certain claims when other stakeholders are not so limited, on the basis of public health, cost containment, and privacy interests. If the Court uses *IMS Health* to continue the trend of expanding First Amendment protections for corporations, both FDA and the states' ability to regulate in this way will be curtailed.

### A. The development of intermediate scrutiny analysis for commercial speech

Over the last three decades, the Supreme Court has expanded First Amendment protection of commercial speech. The commercial speech doctrine first emerged in 1976 in *Virginia State Board of Pharmacy v. Virginia Citizens' Consumer Counsel*, which extended First Amendment protection to truthful commercial speech directed at the public.<sup>8</sup> The court justified the extension of Constitutional rights to non-persons on the grounds that truthful speech by corporations provides valuable information to consumers' purchasing decisions.<sup>9</sup> The focus of

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<sup>8</sup> 425 U.S. 748 (1976) (“[P]eople will perceive their own best interests if only they are well enough informed...”). *Virginia Board* was soon followed by *First National Bank of Boston v. Bellotti*, which held that corporate and individual speech were indistinguishable in terms of informational value to the public. 435 U.S. 765, 777 (1978).

<sup>9</sup> See Darrel Menthe, *The Marketplace Metaphor and Commercial Speech Doctrine: Or How I Learned To Stop Worrying About and Love Citizens United*, 38 *Hastings Const. L.Q.* 131, 136 (2010). Menthe attributes a “public purpose” philosophy to *Virginia Board* in which “the Aim of the First Amendment is not to allow cacophony . . . but to promote the education, learning and organized exchange of ideas that would lead to better . . . public policy.” *Id.* at 138.

the Court was on the value of the information provided by corporation to listeners' decision-making processes, not the speakers' rights to be heard.<sup>10</sup>

In *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, the Supreme Court announced an intermediate scrutiny framework for analyzing First Amendment claims regarding truthful, non-misleading commercial speech. The intermediate scrutiny framework provides less protection for commercial speech than other forms of expression, based on concerns about the reliability of corporate speakers.<sup>11</sup> If under the first element, the commercial speech is truthful and non-misleading the Court will examine whether there is a substantial state interest; whether the regulation directly advances the asserted interest and whether the regulation is not more extensive than necessary.<sup>12</sup> For truthful, non-misleading speech failure to meet any one of the *Central Hudson* elements means that the challenged restriction will be found to be unconstitutional.<sup>13</sup>

Subsequent cases narrowed elements of the *Central Hudson* framework while claiming to leave the overall level of scrutiny intact.<sup>14</sup> This shift may be explained by an overall change in First Amendment theory away from the public good theories of the 1960's and 70's and towards

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<sup>10</sup> Tamara R. Piety, *Citizens United and the Threat to the Regulatory State*, 109 Mich. L. Rev. First Impressions 16, 17 (2010). Advocates of expanded rights for corporate speech contend that regulation constitutes "viewpoint discrimination." This characterization is inconsistent with *Virginia Board's* emphasis on listeners' right to hear what a corporation has to say. *Id.* at 19.

<sup>11</sup> 447 U.S. 557, 562-564 (1980)

<sup>12</sup> *Id.* at 566.

<sup>13</sup> Untruthful or misleading speech is not entitled to First Amendment protection.

<sup>14</sup> For example, in *Rubin v. Coors Brewing Co.*, 514 U.S. 467 (1995) the court found that a ban on alcohol content labeling on beer bottles due to fears about producer competition on the basis of alcohol content did not constitute a substantial interest. In *Florida Bar v. Went for it*, 515 U.S. 618 (1995), and *44 Liquormart v. Rhode Island*, 527 U.S. 484 (1996), the Court found that the challenged statutes lacked did not directly advance the asserted interest. In *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993), and *Edenfeld v. Fane*, 507 U.S. 761 (1993) the Court examined whether the restriction was more extensive than necessary.

a more libertarian ideal of freedom to speak as a good in and of itself.<sup>15</sup> This shift was more or less concurrent with the rise of the “marketplace of ideas” metaphor for First Amendment jurisprudence.<sup>16</sup> The major exception to this trend has been confidential information in the government’s possession, access to which is not protected by the First Amendment.<sup>17</sup>

Since the mid 1990’s, the Court has called into question the appropriateness of the *Central Hudson* framework. In *44 Liquormart, Inc. v. Rhode Island*, Justice Scalia in concurrence and Justice Thomas in dissent questioned whether intermediate scrutiny for commercial speech was constitutionally justified.<sup>18</sup> In *Lorillard Tobacco v. Reilly*, Justice Kennedy joined Justice Scalia’s concurrence stating, “the [*Central Hudson*] test gives insufficient protection to truthful, nonmisleading commercial speech.”<sup>19</sup> Justice Thomas also concurred, stating “when the government seeks to restrict truthful speech in order to suppress the ideas it conveys, strict scrutiny is appropriate, whether or not the speech may be characterized as ‘commercial.’”<sup>20</sup> However, the Court declined to pursue strict scrutiny for commercial speech in *Greater New Orleans Broadcasting Assn, Inc. v. United States* and in *Thompson v. Western*

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<sup>15</sup> See *Menthe* at 142-43.

<sup>16</sup> See *id.* Justice Brennan actually introduced the phrase “marketplace of ideas” to modern Constitutional law, albeit in the context of a place for interpersonal exchange of ideas, rather than economic activity. *Id.* at 142 fn. 56, citing David Cole, *Agon at the Agora: Creative Misreadings in the First Amendment Tradition*, 95 Yale L.J. 857, 894, (1986). Ronald Coase has argued against the potential for consumers to be misled as the reason why commercial speech should receive regular First Amendment protection. See *Menthe* at 145.

<sup>17</sup> See *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984) (confidential information obtained in discovery) and *Los Angeles Police Dept. v. United Reporting Publishing Co.*, 528 U.S. 32 (1999) (arrest records).

<sup>18</sup> 517 U.S. 484, 517, 518 (1996).

<sup>19</sup> 533 U.S. 525, 572 (2001).

<sup>20</sup> 533 U.S. 525, 572 (2001).

*States Medical Center*, with only Justice Thomas holding for strict scrutiny for commercial speech regulation in either case.<sup>21</sup>

Most recently, in *Citizens United v. Federal Elections Commission*, the Court held that political speech by corporations in the form of campaign contributions is entitled to full First Amendment protection.<sup>22</sup> It is hard to imagine the Court will allow a gap between First Amendment protection for corporate political speech and other speech by corporations to persist, given that the Kennedy plurality, equating corporations with individuals, found that “By taking the right to speak from some and giving it to others, the Government deprives the disadvantaged person or class of the right to use speech to strive to establish worth, standing, and respect for the speaker’s voice.”<sup>23</sup>

Given the increasing level of constitutional scrutiny applied to the regulation of corporate speech, it seems likely that both state and federal regulations will be challenged under strict scrutiny for commercial speech, either in name or by the Court’s increasingly strict application of *Central Hudson*. Under the strong showing necessary for First Amendment restrictions to be upheld under strict scrutiny, many extant regulations of commercial speech may be at risk of being ruled unconstitutional. The next section will examine FDA’s prohibition on the promotion of off-label usage by pharmaceutical sponsors, which is arguably similar to Vermont’s Act 80 and similarly likely to be overturned if the Court continues to strengthen First Amendment protection for commercial speech.

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<sup>21</sup> 527 U.S. 173, 197 (Thomas, J. concurring in judgment); 535 U.S. 357, 368 (2002).

<sup>22</sup> 130 S. Ct. 876, 883 (2010).

<sup>23</sup> *Id.* at 881.

### III. FDA's Regulation of Off-Label Promotion

The Food and Drug Administration enjoys expansive regulatory oversight, from foods to cosmetics to medical devices and drugs. “The high purpose of the [FDCA is] to protect consumers who under present conditions are largely unable to protect themselves in this field.” *Kordel v. United States*, 335 U.S. 345, 349 (1948). In regulating drugs, FDA must balance its mandate to protect the public health with the needs of a huge sector of the economy. Further, even in the best of budgetary time FDA operates with limited resources, in which the need for the guaranteed safety and efficacy of drugs on the market must be weighed against the agency's ability to provide effective oversight.<sup>24</sup> FDA's limitation on off-label promotion by the sponsors of approved pharmaceutical drugs is an example of the conflicting demands on FDA's resources and mandate to protect the public health. The basics of FDA's approach, as well as its implications for free speech free speech doctrine will be discussed in this section.

#### A. FDA's Authority to Regulate Off-Label Speech

FDA does not have explicit statutory authorization to regulate off-label promotion of drugs, nor does it have authority to regulate the practice of medicine. Instead, FDA relies on the interplay between the various provisions of FDA's statutory licensing authority. Under the Food, Drug, and Cosmetic Act (“FD&C Act”), new drugs cannot be sold without prior approval from FDA.<sup>25</sup> A new drug is one that is not “generally recognized . . . as safe and effective for use under the conditions prescribed.”<sup>26</sup> In order to sell their product, a drug's sponsor must use

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<sup>24</sup> See U.S. Gov't Accountability Office, Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses, GAO-08-835, at 13 (July 2008) (hereinafter “2008 GAO Report”).

<sup>25</sup> FD&C Act § 505.

<sup>26</sup> 21 U.S.C. 321(p). A drug is “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles . . . intended to affect the structure or any function of the body of man or other animals.” FD&C Act § 201(g)(1)(B)-(C). FDA classifies certain



clinical data to prove that there is substantial evidence of a new drug's safety and efficacy for its intended use.<sup>27</sup> In evaluating a new drug, FDA will weigh the drug's expected benefit to the public against the risk of harm. An approval by FDA is called a New Drug Application ("NDA").

FDA reviews the drug's labeling -- its packaging, container, and inserts -- for compliance with the FD&C Act as a part of the NDA requirements.<sup>28</sup> All intended uses must appear on the drug's label.<sup>29</sup> FDA defines labeling as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."<sup>30</sup> In order to be approved by FDA, drugs must have labels that, *inter alia*, bear "(1) adequate directions for use; and (2) . . . adequate warnings."<sup>31</sup>

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drugs as prescription drugs in order to protect the public health. See, e.g., FD&C Act § 503(b)(3) ("The Secretary may by regulation remove drugs subject to section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health"). A prescription drug is a drug which, "because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such drug . . ." FD&C Act § 503(b)(1), 21 U.S.C. § 353(b)(1) Prescription drugs may only be dispensed upon an oral or written prescription by a licensed practitioner. *Id.*

<sup>27</sup> See *Weinberger v. Hynson, Westcott and Dunning*, 412 U.S. 609 (1973); § 505d; 21 C.F.R. 314.50(d)(5).

<sup>28</sup> 21 U.S.C. §355(b); Defendants' Memorandum of Points and Authorities in Support of Motion to Dismiss or for Summary Judgment, *Allergan v. United States*, 1:09-cv-01879-JDB, Jan. 11, 2010 at 6 (hereinafter MSJ); 21 U.S.C. 355(b)(1)(F). For a general overview of FDA's labeling authority, see Howard L. Dorfman, Vivian M. Quinn, and Elizabeth A. Brophy, Presumption of Innocence: FDA's Authority To Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate, 61 Food Drug Law J. 585 (2006).

<sup>29</sup> 21 CFR § 202.1(e)(4).

<sup>30</sup> 21 U.S.C. 321(m). The term "accompanying" has been given a broad definition by the courts and includes pamphlets distributed with a product. <sup>30</sup> See *Kordel v. United States*, 335 U.S. 345 (1948) ("We conclude that the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported . . ."). Books that promote the sale of specific, brand-name unapproved products. See *United States v. 8 Cartons of "Plantation 'The Original' Recommended and Endorsed by Gayelord Hauser Blackstrap Molasses"* and 25 Copies of a Book Entitled *Look Younger, Live Longer*, by Gayelord Hauser, etc., 103 F.Supp. 626 (W.D.N.Y. 1951).

<sup>31</sup> FD&C Act § 502(f), 21 U.S.C. 352(f); 21 C.F.R. 201.56(a)(1); 21 C.F.R. 201.56(a)(2); *see also* Presentation of Mary E. Kremzner & Steven F. Osborne, *An Introduction to the Improved FDA*

Promotional labeling is defined as other materials distributed or disseminated by the drug's sponsor. Approval of promotional labeling is not part of the NDA. Instead, the drug sponsor submits promotional materials to FDA for review "at the time of the initial dissemination."<sup>32</sup> Drug advertisements fall into this category: FDA does not give pre-approval.<sup>33</sup> Instead, FDA monitors prescription drug advertising *ex post* for omissions of required safety information, or for promotion of unapproved uses that do not reflect the approved label.<sup>34</sup> In addition to agency monitoring efforts, FDA also reviews complaints received from "competitors, health care providers, consumers, and former drug company personnel" who are aware of violations.<sup>35</sup> Both unfair competition claims by competitors and the *qui tam* provisions of the False Claims Act give third parties a way to bring claims of off-label promotion to FDA's attention.<sup>36</sup>

FDA prosecutes violations of its labeling requirements under the FD&C Act's prohibitions on the sale of misbranded products, which deems drugs "misbranded" if the labeling

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Prescription Drug Labeling,  
<http://www.fda.gov/downloads/Training/ForHealthProfessionals/UCM090796.pdf> (last visited May 1, 2011).

<sup>32</sup> *Id.*; 21 CFR 314.81(b)(3)(i), 314.70(a)(4).

<sup>33</sup> MSJ at 7; 21 USC 352(n); 21 C.F.R. §202.1.

<sup>34</sup> *Id.* MSJ at 7, 21 USC 352(n)(3); MSJ at 7; 21 CFR 202.1(e)(4)(i)(a) ) "[A]dvertisements for prescription drugs may not 'recommend or suggest' the drug for unapproved uses.").

<sup>35</sup> *Id.*

<sup>36</sup> For example, John Kopchinski, a former Pfizer sales representative who blew the whistle on Pfizer's off label promotion of Bextra, was awarded \$51.5 million from Pfizer's \$2.3 billion dollar settlement with the Department of Justice in 2009. See Bill Berkrot, "Pfizer Whistleblower's Ordeal Reaps Big Rewards," Reuters.com, Sept. 2, 2009, <http://www.reuters.com/article/2009/09/02/us-pfizer-whistleblower-idUSN021592920090902>. The hook for False Claims Act prosecutions against drug sponsors is reimbursement by government-sponsored health programs such as Medicare and Medicaid for brand name drug prescriptions for off-label uses that were the result of drug sponsor marketing. See Katherine A. Blair, In Search of the Right RX: Use of the Federal False Claims Act in Off-Label Drug Promotion Litigation, 23 No. 4 Health Lawyer 44, 44 (2011).

is “false or misleading in any particular.”<sup>37</sup> An intended use that is not on the label constitutes misbranding because a drug sponsor must “provide adequate directions for all uses that are intended.”<sup>38</sup> FDA deems statements made by drug sponsors that promote off-label uses to be evidence of intended use. Violation of the misbranding provisions can result in FDA warning letters, fines, and prosecution.

FDA’s prosecution of drug sponsors for off label promotion is in stark contrast to the acceptability of off-label usage in clinical settings.<sup>39</sup> For example, physicians’ licenses to prescribe drugs do not prohibit them from prescribing drugs for off-label uses.<sup>40</sup> In addition, public and private payers generally reimburse off-label usage.<sup>41</sup> In some specialties, such as oncology, off-label usage is the standard of care, rather than the exception.<sup>42</sup>

As a result, drug sponsors claim that FDA’s prohibition impedes physicians’ ability to learn about uses that may be of benefit to their patients. However, FDA allows drug sponsors to disseminate certain forms of off-label information such as neutral scientific studies and safety

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<sup>37</sup> FD&C Act § 502(a); 21 U.S.C. 352(a).

<sup>38</sup> MSJ at 8; 21 usc 352(f)(1); 21 CFR 201.5; 201.100(c)(1).

<sup>39</sup> See DC Radley, SN Finkelstein, & RS Stafford, Off-Label Prescribing Among Office-Based Physicians, 166 Archives Internal Med. 1021 (2006) (finding 21% of medications prescribed during sample period were for off-label uses and that most of the off-label usage was not supported by scientific evidence).

<sup>40</sup> See Coleen Klasmeier & Martin H. Redish, Off-Label Prescription Advertising, the FDA, and the First Amendment: A Study in the Values of Commercial Speech Protection, *forthcoming in* 36 Am. J. Law & Medicine (2011).

<sup>41</sup> See Joshua Cohen, Andrew Wilson & Laura Faden, 64 Food & Drug L.J. 391, 397 (2009) (finding three-fourths of public payers surveyed offered reimbursement for off-label prescriptions). Reimbursement for off-label use is not always based on best evidence. *Id.* at 402.

<sup>42</sup> See Dominique Levêque, Off-Label Use of Anticancer Drugs, 9 Lancet Oncology 1102 (2008) (9(11):1102-7; see also WA Meadows & BD Hollowell, “Off-label” Drug Use: An FDA Regulatory Term, Not a Negative Implication of its Medical Use, 20 Int. J. Impotence Res. 135 (2008). In some instances, such as where testing sufficient to obtain FDA approval for a given use may not be possible due to ethical or practical considerations, off-label usage may be the only option. See WF Rayburn, A Physician’s Prerogative To Prescribe Drugs for Off-Label Uses During Pregnancy, 81 Obstetrics & Gynecology 1052 (1993).

information regarding off-label uses.<sup>43</sup> Yet research on off-label usage or medical conferences funded by a drug sponsor are prohibited.<sup>44</sup>

In order to comply with the labeling provisions of the FD&C Act, Manufacturers who want to promote an approved drug for an off-label usage must petition FDA for approval of the off label use.<sup>45</sup> As with an NDA, the sponsor must submit supplemental data on the safety and efficacy of the additional use. Since it can take many years for a drug to gain FDA approval, and the patent period for a new drug lasts twenty years, there may not be sufficient time for a sponsor to get approval for an additional usage before the drug is subject to competition from generics. In addition, the studies required to obtain supplemental approval are very costly, and may not be financially viable the off-label indication is limited in scope. As a result, the incentive for a drug sponsor is encourage off-label usage to the extent that can do so and comply with FDA regulations.<sup>46</sup>

#### B. Policy and Legal Defenses of FDA Regulation of Off-Label Promotion

FDA's ability to regulate off-label promotion, granted by Congress in 1962, comports well with that era's conception of First Amendment protection for speech as stemming from its value as public good, rather than as a private right. FDA has already faced legal challenges to the constitutionality of its prohibition of off-label promotion. Under the *Central Hudson* framework, the government must demonstrate that it has a substantial interest that is protected by the

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<sup>43</sup> See MSJ at 9 (the goal of safe harbors is to promote “unbiased and non-promotional dissemination of truthful and non-misleading information.”); MSJ at 11 (discussion of safety issues related to off-label use allowed “as long as it does not promote the unapproved use.”).

<sup>44</sup> See David A. Kessler & Wayne L. Pines, The Federal Regulation of Prescription Drug Advertising and Promotion, 18 JAMA 264 (1990); *see also* 2008 GAO Report.

<sup>45</sup> S. Rep. No. 87-1744 (1962) (statement of Sens. Kefauver, Carroll, Dodd, Hart & Long).

<sup>46</sup> But see *Washington Legal Foundation v. Henney* (FDA cannot hold drug sponsor's First Amendment rights hostage to regulatory scheme, despite substantial interest in encouraging supplemental NDA's).

restriction on commercial speech. This section will examine the policy interests claimed by FDA, as well as the legal arguments that FDA uses to try to exempt off-label promotion from First Amendment scrutiny entirely.

i. FDA Prohibits Off-Label Promotion on the Basis of Public Health Policy

Congress granted FDA the authority to regulate off-label claims as part of the 1962 revisions to the FD&C Act.<sup>47</sup> Without the ability to regulate what drug sponsors say about their product after they have received FDA approval, the pre-market approval process would be rendered meaningless.<sup>48</sup> Manufacturers would submit NDA's on the easiest claim to justify, but then promote the drug for other uses after approval without being subject to evaluation for safety and efficacy.<sup>49</sup> FDA claims that there is a great potential for harm to the public if the market were to return to this state.<sup>50</sup>

However, FDA's concerns about protecting the public health fail to take into account prescribers' roles as intermediaries between patients and drug sponsors. Regardless of the drug sponsor's claims as to whether a drug is indicated for a certain condition, the prescriber is the one who ultimately decides whether it is appropriate for a patient.<sup>51</sup> Thus, FDA's concerns of snake oil salesmen and patent medicine are arguably circumscribed by FDA regulations that require drugs with potential for dangerous side effects to be dispensed by prescription only.

A second policy argument for FDA's attempts to limit off-label promotion is that physicians should receive unbiased information. The assumption is that drug sponsors will not

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<sup>47</sup> S. Rep. No. 87-1744 (1962) (statement of Sens. Kefauver, Carroll, Dodd, Hart & Long).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*; MSJ at 16-17.

<sup>50</sup> MSJ at 12, fn8.

<sup>51</sup> See, e.g., Alexander D. Baxter, *IMS Health v. Ayotte: A New Direction on Commercial Speech Cases*, 25 Berkeley Tech. L.J. 649, 656 (2010).

share negative information with prescribers if they are not required to do so.<sup>52</sup> The difference between approved uses and off-label uses is that, while a sponsor of an approved drug would also be expected to present its product in the best possible light, FDA requires that the product's labeling include side effects and contraindications. For an off-label use, which could occur at a different dosage or regimen than the approved use, the warnings and cautions required to be on the label may not be relevant. In emphasizing the potential for prescribers to be misled based on pre-1962 behavior of drug manufacturers, FDA attempts to distinguish its regulation from *Thompson v. Western States Medical Center*, which struck down a prohibition on truthful, non-misleading commercial speech.<sup>53</sup>

At third argument for why FDA should have the power to regulate off-label promotion by drug sponsors is FDA's unique capacity to evaluate safety and efficacy claims. If FDA cannot not prevent misbranded drugs from coming on the market, it would be forced to rely on its libel and seizure powers in order to remove drugs from the market that lack NDA's. FDA and drug sponsors would then litigate the safety and efficacy of a particular product in the courts, rather than relying on FDA's expertise and established review procedures.<sup>54</sup> In addition, FDA's seizure remedy is incomplete – a dangerous product may remain on the market and continue to threaten public health while the litigation drags on.<sup>55</sup>

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<sup>52</sup> *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999) (“the manufacturers’ dissemination of such information is likely to be misleading because manufacturers have an incentive to disseminate information that presents their drugs only in a positive light, omitting negative information and failing to provide the ‘balance’ that FDA would prefer.”).

<sup>53</sup> MSJ at 13, citing *Thompson v. Western States*, 535 U.S. 357, 374 (2002).

<sup>54</sup> MSJ at 17.

<sup>55</sup> *Id.*

ii. Legal Challenges to FDA's Off-Label Promotion Ban: *Allergan v. United States*

As discussed *supra*, a drug sponsor's promotion of unapproved uses for its product is a violation of the FD&C Act because it renders the drug mislabeled. FDA considers promotional speech regarding unapproved uses to be evidence of intent to distribute a mislabeled drug. FDA considers the sponsor's objective intent of the speech in order to determine whether a violation has occurred.<sup>56</sup> Objective intent can "be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."<sup>57</sup> Thus, FDA can be said to use commercial speech, among other things, to establish intent to violate the FD&C Act. In criminal cases, the Supreme Court has upheld the use of what defendant said to establish a hate crime, over defendant's First Amendment objection.<sup>58</sup>

In *Whitaker v. Thompson*, the DC Circuit upheld in FDA's contention that it is regulating conduct, not commercial speech.<sup>59</sup> However, *Whitaker* involved structure function claims made for a nutritional supplement that had not been approved for any use by FDA, whereas FDA's off-label enforcement actions involve drugs that *have* been approved by FDA, albeit not for the uses for which they are being promoted. Unfortunately, courts have not directly addressed the question of whether FDA's off-label prohibitions should be subject to intermediate scrutiny.<sup>60</sup>

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<sup>56</sup> MSJ at 8.

<sup>57</sup> MSJ at 8; 21 CFR 201.128.

<sup>58</sup> *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993) ("[t]he First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.").

<sup>59</sup> 353 F.3d 947, 953 (D.C. Cir. 2004) ("it is constitutionally permissible for the FDA to use speech . . . to infer intent for purposes of determining that the proposed sale would constitute the forbidden sale of an unapproved drug.")(citing *Mitchell*).

<sup>60</sup> See, e.g., *United States v. Caputo*, 517 F.3d 935, 938-940 (7th Cir. 2008) (considering defendant's First Amendment claims but not reaching them on grounds of medical device manufacturer's flagrant violations of the FD&C Act constituted unlawful acts); *United States v. Caronia*, 576 F. Supp. 2d 385, 394 (E.D.N.Y. 2008) ("[T]he constitutional issues . . . are very much unsettled, not only in this circuit but nationwide.").

In 2009, Allergan, the manufacturer of Botox, petitioned the D.C. District Court to enjoin FDA's enforcement of its off-label provisions.<sup>61</sup> Allergan's grounds for the injunction were that FDA's classification of truthful, non-misleading marketing information as labeling violated Allergan's First Amendment rights, or, in the alternative, that FDA's regulatory interpretation of the statutory definition of labeling was unreasonable.<sup>62</sup> In its Complaint, Allergan, framing the dispute in terms of its "right" to speak about its products, emphasized that FDA's prohibition on off-label promotion depends on who is the speaker is: drug sponsors are subject to enforcement, whereas independent physicians and researchers are not.

In *Allergan*, FDA argued that *Central Hudson* should not apply because *Central Hudson* only applies to lawful and non-misleading speech. Since the sale of a drug with intended, but unapproved, uses is an illegal act under the FD&C Act, the promotional speech does not receive First Amendment protection. The problem with this argument is that the act itself – the off-label use of prescription drugs – is not illegal.<sup>63</sup> Thus, FDA's argument against promotional speech rested on the assumption that speech by drug sponsors about prescription drugs is of less value to

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<sup>61</sup> See Complaint, *Allergan, Inc. v. United States*, No 1:2009cv01879, Oct. 1, 2009. FDA argued that Allergan's claims were unripe, since its application pediatric use was still pending at the time of the lawsuit, and moved to dismiss on those grounds.

<sup>62</sup> See Complaint at ¶ 108. The regulation at issue is 21 C.F.R. § 202.1(l)(2):

Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the Act.

§ 201(m), discussed *supra*, is the statutory definition of labeling. Allergan's second claim would be subject to review under the principles of the *Chevron* doctrine and would not be impacted by the Supreme Court's forthcoming decision in *IMS Health*.

<sup>63</sup> In fact, off-label uses are reimbursed by CMS, albeit under a different evidentiary standard than the one used by FDA. See MSJ at 41.



the public than that made by other non-commercially motivated speakers. In light of the shift towards assessing speech as an individual right rather than as a contribution to public knowledge and understanding, FDA's argument failed to address the balancing of interests inherent to *Central Hudson* and its progeny.

In response, FDA argued that a drug sponsor's marketing materials that contain claims regarding off-label usage constitutes intent to engage in off-label promotion.<sup>64</sup> As discussed *supra*, FDA uses the argument that this is conduct, not speech, therefore its off-label prohibitions should not be subject to *Central Hudson*'s intermediate scrutiny.<sup>65</sup> However the court did not have the opportunity to evaluate FDA's claim because Allergan dismissed its case against FDA as part of a larger settlement with DOJ. In the settlement, Allergan admitted to marketing Botox for unapproved uses and pled guilty to a criminal misdemeanor and paid over \$500 million to settle FD&C Act misbranding claims and False Claims Act charges.<sup>66</sup>

Despite not being resolved by the District Court, Allergan's viewpoint discrimination claim is a preview of the types of First Amendment claims that can be expected in drug sponsor litigation against FDA. If the Supreme Court opens the door to First Amendment claims by drug sponsors by holding the Vermont statute subject to an increased level of scrutiny or abandoning the *Central Hudson* framework in favor of full First Amendment protection for commercial speech, FDA may have to prove that the prohibition on off-label promotion by drug sponsors does not violate the First Amendment. Given holdings such as *Washington Legal Foundation v. Henney*, which found that fears of being misled are not a significant government interest, the

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<sup>64</sup> 21 C.F.R. § 201.128.

<sup>65</sup> See 56 F. Supp. 2d 81 (D.D.C. 1999). For a more complete discussion of the commercial speech doctrine, see Section II, *supra*.

<sup>66</sup> See Natasha Singer, *Maker of Botox Settles Inquiry*, New York Times, Sept. 1, 2010 at A1.

policy reasons discussed *supra* may not be enough to demonstrate that the off-label prohibitions protect a substantial government interest.<sup>67</sup>

FDA limits drug sponsors to use claims approved in an NDA out of concerns for public health. FDA does not, however, limit what others – such as academics, governments, and private physicians, can say about off-label uses for an approved drug. It does not prohibit prescribers, acting as fiduciaries for their patients, from prescribing drugs for unapproved uses, nor does it prevent the government or private payers from funding such uses. FDA has some defenses to a drug sponsor’s claim of First Amendment infringement. If the Court holds against Vermont on the basis of viewpoint discrimination in *IMS Health*, these defenses could be at risk. The next section will give a brief background on the *IMS Health* litigation and examine potential outcomes in light of their impact on FDA regulation of off-label promotion.

#### IV. *IMS Health, Inc. v. Sorrell* and Government Regulation of Pharmaceutical Marketing

Vermont’s 2007 enactment of An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information<sup>68</sup> (“Acts 80”) was part of a larger effort by the states of Vermont, New Hampshire, and Maine to reduce the impact of new pharmaceutical marketing techniques on the prescription of brand-name drugs to their citizens. This section will first briefly describe pharmaceutical data mining, which is the marketing practice at issue. Then Vermont’s statute, and the attendant litigation, will be compared to that of Maine and New Hampshire. Finally, the arguments presented to the Supreme Court in the Vermont litigation will be summarized.

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<sup>67</sup> 56 F. Supp. 2d 81(D.D.C. 1999).

<sup>68</sup> Vt. Stat. tit. 18, § 4631 (2009).

## A. Pharmaceutical Data Mining

Pharmaceutical data mining, which in this context is the use of prescription records to target marketing pitches to physicians,<sup>69</sup> is controversial because it uses physician data for non public health purposes without permission. The pharmaceutical data mining industry began to emerge in the early 1990's after the development of computer systems installed in pharmacies made the collection and transmission of pharmacy data feasible.<sup>70</sup>

When a customer fills a prescription, pharmacies retain information about the transaction. This information includes patient name, physician identity, drug, dosage, and quantity.<sup>71</sup> The pharmacy also transmits information necessary for the payment of pharmacy benefits to third party payers, primarily insurance companies and pharmacy benefits managers in order to complete the transaction.<sup>72</sup> The data is also available for purchase by third party data miners that analyze the data and provide reports to pharmaceutical companies on market trends.<sup>73</sup> The legislation at issue targets the purchase of prescription data by data miners from pharmacies.

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<sup>69</sup> Data mining is a catch-all term for analysis of large data sets for trends that may otherwise be non-obvious and is not necessarily invidious. Thus, the pharmaceutical industry and its regulators use data mining for purposes other than marketing. For example, researchers use data analysis tools to identify compounds that may be pharmacologically active, or cause drug-drug interactions, based on fit. See FDA also engages in data mining as part of its post-marketing surveillance activities in order to identify significant trends in adverse drug events that could signal a problem with an approved product.

<sup>70</sup> *Id.* (citing statement of Pat Glorioso, IMS Health marketing executive).

<sup>71</sup> See *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 45 (1st Cir. 2008).

<sup>72</sup> See *id.*

<sup>73</sup> Due to federal privacy regulations, such as HIPAA, the prescription data identifies the prescriber (either by name or by license number) but does not include the patient's name. Although patient privacy interests were not found to be at stake by the Vermont Legislature and the issue has not been argued in this case, there are concerns about whether this is actually the case. See Jennifer L. Klocke, Note, Prescription Records for Sale: Privacy and Free Speech Issues Arising from the Sale of De-Identified Medical Data, 44 *Idaho L. Rev.* 511, 514 (2008); Brief of Amici Curiae Electronic Privacy Information Center (EPIC) and Legal Scholars and Technical Experts in Support of the Petitioners, No. 10-779, Mar. 1, 2011; Paul Ohm, Broken Promises of Privacy: Responding to the Surprising Failures of Anonymization, 57 *UCLA L. Rev.* 1701 (2010).

## B. Vermont's Prohibition on the Sale of Pharmacy Data for Marketing Purposes

In 2007, Vermont enacted Acts 80, which was modified by Acts No. 89 in 2008. The legislature found that pharmaceutical marketing in general had a negative impact on public health.<sup>74</sup> § 17 targeted detailing, which is visits to physician offices by pharmaceutical company representatives for sales purposes. The legislature believed that detailing practices were being exacerbated by access to prescription prescribing records.<sup>75</sup> §17 thus requires physician consent for their prescribing data to be shared with data miners.<sup>76</sup> Acts 80 also creates a variety of exceptions to the rule for third parties that promote state interests in public health or cost

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<sup>74</sup> The Legislature found that marketing activities may conflict with the State's goals of cost containment and protecting the health of its citizens. See Acts No. 80 at § 1(1) – (18). Vermont also found that pharmaceutical marketing visits were increasingly aggressive, *id.* at §§ 1(22); (27)-(28), and violated physician expectations of privacy. *Id.* at § 1(29).

Vermont made its detailed findings after the Maine and New Hampshire statutes were challenged by IMS Health on First Amendment grounds. Maine and New Hampshire enacted their restrictions on pharmaceutical data mining of prescriber-identified data prior to Vermont. See Prescription Information Law N.H. Rev. Stat. §§ 318:47-f, 318:47-g, 318-B:12(IV); 22 Me. Rev. Stat. § 1711-E (1-A, 1-B) (2009). Both states made general findings about their laws. The New Hampshire General Court stated that its purpose was to protect privacy, health care quality, and contain costs. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 47 (1st Cir. 2008). Similarly, the Maine Legislature made express findings that the law was intended to improve public health, contain costs, and protect privacy. *IMS Health Inc. v. Rowe*, 532 F.Supp.2d 153 (D. Me. 2007).

<sup>75</sup> See *IMS Health v. Sorrell*, 630 F.3d 263, 267 (2010).

<sup>76</sup> The language at issue is:

“A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents as provided in subsection (c) of this section. Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section.

18 Vt. stat. ann. § 4631(d) (2010).

containment, such as entities engaged in disease surveillance, the promotion of generic drugs, or academic studies.<sup>77</sup>

### C. IMS Health's First Amendment Challenge to Vermont Acts 80, § 17

In August 2007, IMS Health, Inc. and PhRMA filed separate suits against the Vermont attorney general seeking an injunction against the enforcement of Acts 80, § 17. The lawsuits were consolidated in November 2007. The Vermont District Court, after a bench trial, found for Vermont on the basis that § 17 survived *Central Hudson's* intermediate scrutiny elements.<sup>78</sup> IMS Health and PhRMA appealed on the basis that § 17 should not survive intermediate scrutiny, or, in the alternative, that the District Court should apply strict scrutiny.<sup>79</sup>

Vermont argued that § 17 is an exercise of its right to restrict access to government information. However, the Second Circuit distinguished § 17 from *Los Angeles Police Department v. United Reporting Publishing Corp.* on the basis that the data was actually in possession of the pharmacies, not the state.<sup>80</sup> The Second Circuit also dismissed the First Circuit's finding that similar Maine and New Hampshire statutes regulated a commodity, rather than speech, on the basis that, under *United States v. Stevens*, courts cannot "declare new categories of speech outside the scope of the First Amendment."<sup>81</sup>

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<sup>77</sup> Id. at § 4631(e)(1)-(7). According to Vermont's statements to the Supreme Court, the data can be sold for non-marketing purposes, however that is not actual practice. See Transcript of Oral Argument, *Sorrell v. IMS Health*, No 10-779, Apr. 26th 2011 at 11:9-13.

<sup>78</sup> See *IMS Health, Inc. v. Sorrell*, 631 F. Supp. 2d 434, 455 (2009).

<sup>79</sup> *IMS Health*, 630 F.3d at 271.

<sup>80</sup> Id. at 273.

<sup>81</sup> Id. at 272, citing 130 S. Ct. 1577 (2010) (holding that statute criminalizing "crush" pornography constitutes a facially invalid content restriction). See also Alexander D. Baxter, *IMS Health v. Ayotte: A New Direction on Commercial Speech Cases*, 25 Berkeley Tech. L.J. 649, 669 (2010) (describing why other Circuits are unlikely to follow the First Circuits classification of data mining as conduct, not speech).

The Second Circuit analyzed IMS Health’s claims under *Central Hudson* and found that Vermont’s asserted interest in physician privacy was “too speculative to satisfy the second prong of *Central Hudson*,” although the state interests in cost containment and protecting public health did qualify.<sup>82</sup> However, the Second Circuit held that, under the fourth prong, “[t]he Vermont statute cannot be said to advance the state’s interests in public health and reducing costs in a direct and material way.”<sup>83</sup> The court also found in dicta that there were more limited restrictions available to Vermont, such as state-sponsored generic drug promotion and mandated generic drug substitution.<sup>84</sup>

C. *Sorrell v. IMS Health, Inc.*

The State of Vermont petitioned for certiorari on the basis that the Second Circuit’s holding had created a circuit split between the First and Second Circuits,<sup>85</sup> and was granted cert

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New Hampshire’s provision completely banned the sale or transfer of “patient-identifiable and prescriber-identifiable data” for any commercial purpose.” N.H. Rev. Stat. § 318.47-f (2009). Commercial purpose was broadly defined and included “advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product . . .” *Id.* Maine’s statute, on the other hand, created a system under which physicians could opt-out of inclusion in data sold to data miners.<sup>81</sup> Thus, each of these three provisions is slightly different in terms of physician inclusivity.

In both states, IMS Health challenged the restrictions on data mining on First Amendment grounds. District Courts in both states held the restriction unconstitutional on *Central Hudson* grounds. *See* *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 183 (D.N.H. 2007); *IMS Health Inc. v. Rowe*, 532 F.Supp.2d 153 (D. Me. 2007). Both states appealed. The Maine litigation was stayed pending the outcome of the New Hampshire case. The First Circuit reversed the District Court and held that the New Hampshire statute did not regulate speech. *See* *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 52-53, 54 (1st Cir. 2008). Rather, the court held that the transaction at issue between two private parties was akin to the regulation of the sale of “beef jerky.”<sup>81</sup> IMS Health appealed to the Supreme Court, which denied certiorari.<sup>81</sup> The Maine statute was subsequently upheld in *IMS Health, Inc. v. Mills*, 616 F.3d 7 (2010).

<sup>82</sup> *Id.* at 276.

<sup>83</sup> *Id.* at 277 (finding that making marketing less effective did not constitute direct cost controls or protection of the public health).

<sup>84</sup> *IMS Health*, 630 F.3d at 280.

<sup>85</sup> Petition for a Writ of Certiorari, Dec. 13, 2010.

on January 7, 2011.<sup>86</sup> The parties exchanged briefs in March, and Vermont submitted its reply brief on April 15. This section will briefly summarize the most salient arguments made by the parties and some of their amici prior to oral argument.

i. § 17 as a restriction on nonpublic information

Vermont contends that because it and FDA require the collection of data on prescribers, and because prescription records are non-public information, § 17 is a constitutional restriction of nonpublic information.<sup>87</sup> Vermont, along with the United States as amicus curiae, argue that the Court’s holdings in *Seattle Times v. Rhinehart* and *LAPD v. United Reporting*, which upheld restrictions on access to nonpublic should be extended to cover prohibitions on third parties who hold data pursuant to government regulations.<sup>88</sup> Vermont argues that presence of its regulatory system therefore takes the data at issue out of intermediate scrutiny because it is not subject to First Amendment protection at all.

Respondents emphasize that the data at issue “is privately created, privately collected, and privately owned,” and therefore the government data cases barring First Amendment

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<sup>86</sup> *Sorrell v. IMS Health Inc.*, 131 S.Ct. 857 (2011) (Memo). Whether it was appropriate for the Court to grant cert in this case is an open question, since the First and Second Circuits made different findings on the facts as to whether state anti-data mining legislation restricts speech or conduct.

There are also questions as to why the Court granted cert in *Snyder v. Phelps*, a First Amendment case decided earlier in the term. 131 S. Ct. 1207 (2011); see Alan Brownstein & Vikram David Amar, *Afterthoughts on Snyder v. Phelps*, 2011 Cardozo L. Rev. de novo 43, 43-45 (2011). Case law already supported the Circuit Court’s holding and no circuit split exists on the issue of the constitutionality of damages awards for the type of IIED claim at issue in *Snyder*, although a serious split exists regarding content-neutral time, place and manner restrictions on picketing. Brownstein Amar at 43-45.

<sup>87</sup> Brief for Petitioners, No 10-779, at 23-27 (hereinafter “Vermont Brief”); Reply Brief for Petitioners, 2011 WL 1462744, Apr. 15, 2011 at \*5 (citing *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984) (hereinafter “Reply Brief”).

<sup>88</sup> Brief for the United States as Amicus Curiae Supporting Petitioners at 12-16 (hereinafter “U.S. Brief”)

protection to government data do not apply.<sup>89</sup> Respondents contend that pharmacies would collect the government-mandated information in the absence of regulation because it is necessary for insurance reimbursement submissions,<sup>90</sup> and that the data is willfully provided by the pharmacies to Respondents.<sup>91</sup> Finally, Respondents distinguish § 17 from *Seattle Times* on the grounds that Vermont’s legislation is not facially neutral, whereas the statute at issue in *Seattle Times* was.<sup>92</sup>

ii. *Central Hudson* Analysis

In the alternative, Vermont argues that the protection of its interests in public health, physician privacy, and state cost containment constitute a substantial interest under the *Central Hudson* framework.<sup>93</sup> As to the third *Central Hudson* element, Petitioner and its amici point to findings by the state legislature as to the risks and costs of prescription drug marketing.<sup>94</sup> As to the last *Central Hudson* element, reasonable fit between a regulation’s means and ends, the legislature did not choose to enact a complete ban on marketing by pharmaceutical companies.<sup>95</sup>

Respondents dispute the substantiality of Vermont’s stated interests. They question § 17’s ability to protect patient privacy, since other stakeholders, such as insurers and pharmacy

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<sup>89</sup> Brief for Respondent Pharmaceutical Research and Manufacturers of America at 56 (hereinafter “PhRMA Brief”).

<sup>90</sup> *Id.* at 58.

<sup>91</sup> See Brief of Respondents IMS Health Inc., Verispan, Inc., and Source Healthcare Analytics, Inc. at 22 (hereinafter “IMS Health Brief”).

<sup>92</sup> *Id.*

<sup>93</sup> U.S. Brief at 23-24; Reply Brief at \*23-24 (discussing public health risks of new prescription drugs).

<sup>94</sup> Brief for the States of Illinois, Alabama, Arizona, Arkansas, California, Colorado, Delaware, Georgia, Hawaii, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Minnesota, Mississippi, Montana, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Washington, and West Virginia and the District of Columbia as Amici Curiae in Support of Petitioners at 29-31 (hereinafter “States’ Brief”).

<sup>95</sup> States’ Brief at 36.



benefits managers, have access to the same information that pharmaceutical companies are prohibited to have.<sup>96</sup> Further, PhRMA argues that Vermont's claims regarding the public health fails to appreciate the extensive FDA NDA process.<sup>97</sup> Finally, Respondents deny that cost containment is a valid interest because the relationship between pharmaceutical marketing and Vermont's health care costs is unproven.<sup>98</sup>

Respondents also attack § 17 for failing to directly and materially advance the asserted interests, since it impedes marketing pitches about drugs for which a generic substitute is unavailable or for which no other drug is available in the same way that it impedes marketing pitches for prescription drugs for which there are low-cost alternatives.<sup>99</sup> Similarly, IMS Health points out that the law targets the marketing of safe and unsafe drugs alike, and Vermont has not shown that the unsafe drugs are the ones being promoted via detailing visits.<sup>100</sup> As for the fourth prong, PhRMA claims that § 17 Vermont already has other, non-infringing programs available to it to promote health care cost reduction, such as mandatory generic substitution statutes and educational programs, therefore the regulation is more extensive than necessary.<sup>101</sup>

### iii. Strict scrutiny

PhRMA asserts a second argument for strict scrutiny -- that the Vermont statute constitutes viewpoint discrimination against pharmaceutical companies and is therefore presumptively invalid, citing "fighting words" cases such as *R.A.V. v. City of St. Paul*.<sup>102</sup>

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<sup>96</sup> PhRMA Brief at 30-40; IMS Health Brief at 35-47.

<sup>97</sup> PhRMA at 49-50.

<sup>98</sup> PhRMA Brief at 51-52; IMS Health Brief at 47-49.

<sup>99</sup> PhRMA Brief at 52; IMS Health Brief at 57.

<sup>100</sup> IMS Health Brief at 57; 59.

<sup>101</sup> PhRMA Brief at 54-55.

<sup>102</sup> *Id.* at 23.

PhRMA claims that Vermont is interfering with its ability to speak “about the safety and efficacy of FDA-approved medicines, a subject open to public debate,” because it represents the interests of pharmaceutical companies, whereas other health care stakeholders may use prescriber-identified data.<sup>103</sup> PhRMA couches its objection in the language of “interference with the marketplace of ideas”<sup>104</sup> and “paternalism towards consumers.”<sup>105</sup>

Vermont argues against PhRMA’s call for strict scrutiny on the basis that it fails to meet the *Dun & Bradstreet* requirement of “matters of public importance” because the data is proprietary to the data mining companies, produced for individual clients, and purchasers are prohibited from dissemination.<sup>106</sup> Vermont disputes Respondents’ claims of “invidious discrimination” on the basis that parties that are allowed to access the data, such as insurers, do so for different purposes, such as claims processing and formulary compliance, than pharmaceutical companies.<sup>107</sup> Further, Vermont claims that the discrimination asserted by Respondents ignores the different factual and legal relationships between health care stakeholders such as insurers, providers, and patients, on the one hand, and vendors of health care supplies, such as pharmaceutical companies, on the other, particularly when the allowed uses, such as research, are not commercial speech.<sup>108</sup> Finally, Vermont and a coalition of attorneys general for thirty-five states and the District of Columbia also urge the Court to consider the negative impact of strict scrutiny for First Amendment claims against other Federal

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<sup>103</sup> Id. at 25.

<sup>104</sup> Id. at 33

<sup>105</sup> Id. at 27-30.

<sup>106</sup> Reply Brief at \*6-7.

<sup>107</sup> Reply Brief at \*10.

<sup>108</sup> Reply Brief at \*13. Vermont mentions FDA’s prohibition of off-label speech as one regulatory scheme that would be in jeopardy under Respondents’ “equal footing” argument. Id.

and State privacy regulations, since much of IMS Health’s claim for strict scrutiny on the basis of viewpoint discrimination would also apply to other privacy regulations that allowed for exceptions to some parties based on their interests.<sup>109</sup>

#### V. Analysis of Potential Holdings in *Sorrell v. IMS Health* and Their Impact on FDA’s Off-Label Prohibitions

At oral argument, the Court confined its line of questioning to a limited number of topics.<sup>110</sup> Some lines of questioning would lead to outcomes that could be neutral for FDA, although they could still lead to Vermont’s law being struck down. Other outcomes range from negative to devastating to FDA’s regulation of off-label promotion by drug sponsors. The Court did not appear to give serious consideration to Vermont’s assertion that it was regulating speech, not conduct. Thus, I feel that the most likely outcomes for this case is an evaluation of Respondents’ claims under some level of First Amendment scrutiny.

If the Court utilizes the *Central Hudson* framework, it is likely to return a finding of either no substantial state interest, or of a lack of reasonable fit between the asserted interest and the regulation of speech. Another outcome that is more damaging from FDA’s perspective would be a finding of “viewpoint discrimination” and the application of strict scrutiny. Finally, the most unlikely holding, since it would require overruling *Central Hudson* outright, would abandon the distinction between commercial and non-commercial speech. Other outcomes under ancillary issues raised at oral argument are also possible and would not reach FDA’s off-label prohibitions. This section will examine each of these potential outcomes and explain their impact on FDA.

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<sup>109</sup> See Reply Brief at \*6-9; States’ Brief at 9-16. The Solicitor General argues that a ruling adverse to Vermont would not affect federal privacy legislation because it is “not analogous” to Vermont’s law. U.S. Brief at 33-35.

<sup>110</sup> See Transcript of Oral Argument, Apr. 26, 2011.

A. Outcome One: The Court Affirms the Second Circuit Under the *Central Hudson* Framework

A large number of questions from Justices explored the interests asserted by the state of Vermont in enacting §17, per *Central Hudson*'s substantial interest prong. Both Chief Justice Roberts and Justice Scalia questioned how § 17 could purport to protect physicians' prescribing data if that data was inevitably released to insurers, academics, and the government as part of their role as health care stakeholders.<sup>111</sup> Justice Alito observed that the statute does not give prescribers protection from these other health care entities, and Chief Justice Roberts also pointed out that physicians cannot opt out of the academic use of their information.<sup>112</sup> Given the level of skepticism on the Court, it appears likely that Vermont's asserted interest in protecting physician privacy will not be recognized as a substantial interest. If the Court holds for Respondents on this ground, it would have little impact on FDA's regulations, since FDA can assert stronger interests in public health.

In contrast, the Court appeared to accept cost control as a substantial interest, and evaluated whether restricting access to pharmacy data directly advanced Vermont's financial interest and whether it was more broad than necessary, in a mix of the third and fourth *Central Hudson* prongs. Justice Ginsberg questioned whether Vermont was impermissibly restricting speech by pharmaceutical companies in favor of generic manufacturers in order to reduce

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<sup>111</sup> See Transcript at 11:14-18 (Justice Scalia: How does it increase the prescribing physician's right of privacy that the data about his prescribing can only be given away but can't be sold? Does that make him feel happier about his privacy?).

<sup>112</sup> Tr. 27:20-25.

costs.<sup>113</sup> Justice Kennedy similarly questioned why Vermont was controlling health care costs through speech. Chief Justice Roberts pointed out that under prior precedent, the restriction on access to information by an interested party is Constitutionally problematic.<sup>114</sup> Justice Scalia opined that the statute only prevents “really effective speech” – pharmaceutical detailers would still be able to send in their detailers to physician’s offices, albeit at a lower return on investment than before.<sup>115</sup> Chief Justice Roberts also observed that what the Vermont statute accomplishes is that it “[makes] it far more burdensome for the manufacturers to reach their intended audience . . .”<sup>116</sup>

Thus, it appears likely that, even if the court holds that cost containment is a substantial interest, § 17 could also be struck down as failing to directly advance the state’s interests. This holding would be similarly low-risk as a finding of no substantial interest in protecting physician privacy because FDA uses public safety in terms of the stability of its regulatory scheme, rather than cost containment as its major policy justification for the restriction on off-label promotion.

B. Option Two: The Court Rejects Vermont’s Contention that § 17 Regulates Access to Data, Not Speech

Several justices scrutinized Vermont’s claim that *LAPD* and *Seattle Times* should be extended to include limitations on access to data collected by private parties pursuant to a government regulatory scheme. Chief Justice Roberts and Justices Kennedy and Breyer presented Respondents with hypotheticals that explored whether regulation of access to this type of information would be appropriate in other contexts. Roberts analogized to restrictions on

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<sup>113</sup> Tr. 14:3-11.

<sup>114</sup> Tr. 27:9-14.

<sup>115</sup> Tr. 16:20-23.

<sup>116</sup> Tr. 15:15-23.

access to his tax return,<sup>117</sup> Kennedy questioned whether the outcome would be analogous to *LAPD* if Vermont restricted the sale of data to everyone,<sup>118</sup> and Breyer examined whether the restriction on use could include an exception for emergency purposes and still qualify.<sup>119</sup> Given the amount of time that the Court spent on evaluating the *Central Hudson* factors, the Court seems unlikely to uphold the Vermont statute on the grounds that it regulates access to data not protected by the First Amendment. Since this argument would not be the basis for a holding against Vermont, the impact on FDA would be minimal either way.

### C. Option Three: The Court Finds Vermont’s Statute Constitutes Viewpoint Discrimination

The Court spent a substantial amount of time exploring Respondents’ claim of viewpoint discrimination, which may indicate that the Court will seriously consider the claim in deciding the case. In addition, the prior term’s decision in *Citizens United v. FEC*, in which a plurality delivered by Kennedy, and consisting of Roberts, Scalia, Alito, and Thomas held that limitations on campaign contributions by corporations constituted viewpoint discrimination, enhances the potential for an extension of full First Amendment protection for commercial speech in cases where the government has engaged in viewpoint discrimination.

A finding of viewpoint discrimination would mean that Vermont’s statute is presumptively invalid, and the Court could do so without having to overturn *Central Hudson*, which could still apply to commercial speech cases where there was no viewpoint discrimination. At oral argument, as part of a longer line of questioning regarding neutrality, Chief Justice Roberts presented a viewpoint hypothetical, stating “What if the statute said this information is going to be used for any purpose except not for anybody who is going to criticize the State of Vermont?”

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<sup>117</sup> Tr. at 62:9-23.

<sup>118</sup> Tr. at 52:16-24.

<sup>119</sup> Tr. at 51:2-8.

Except a purpose that will make things more expensive for the State of Vermont?”<sup>120</sup> Similarly, Justice Ginsberg questioned Vermont’s decision to “lower the decibel level of one speaker so that another speaker, in this case the generics, can be heard better?”<sup>121</sup>

A finding of viewpoint discrimination would be disastrous for FDA’s off-label regulation because the viewpoint discrimination claim comes from the fact that, in the Vermont statute, pharmaceutical companies are being limited in their ability to speak as effectively as other parties about their products. This differentiation on who gets to speak based on who they are is easily analogized to FDA’s prohibition on off-label speech by pharmaceutical companies, despite allowing anyone who does not have a commercial interest in the sale of drugs to promote off-label uses for a company’s product. If this is the outcome of *IMS Health*, FDA will have to distinguish its regulations from the Vermont statute, however a finding of viewpoint discrimination will be almost impossible for FDA to overcome on interests such as public health and regulatory efficiency, discussed *supra*.

#### D. Case Four: Other Potential Outcomes

There are a few remaining possibilities for what the Supreme Court will decide in *IMS Health*. As an initial matter, the above assessments have focused on what are likely to be majority or plurality opinions. The minority may well hold for Vermont or Respondents on grounds not covered here. In addition, there are a few grounds on which the Court could avoid creating new precedent. First, there is a potential discrepancy between the Second Circuit’s understanding of whether §17 permitted the sale of pharmacy data to non-pharmacy parties, which could alter the Second Circuit’s analysis of whether the statute directly advances

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<sup>120</sup> Tr. at 28:10-19.

<sup>121</sup> Tr. at 14:3-11.

Vermont's asserted interests. The Second Circuit claimed that the statute did allow sale to other parties, however Vermont, along with the United States, claims that it does not and that the issue was not fully briefed below. Thus, the case could be remanded for further consideration.

Another possibility is that the Court will attempt to distinguish between Vermont's opt-in provision and the total ban and opt-out provisions considered by the First Circuit. Although Justice Sotomayor was the only justice who pursued the issue at oral argument, there may be enough to distinguish the cases based on the structure of the law and thus cabin the judgment somewhat.<sup>122</sup> In any case, neither outcome would have an immediate impact on FDA regulation of off-label promotion.

A final outcome of this case could be that the Court will take it as an opportunity to abandon the Central Hudson framework entirely in favor of strict scrutiny for limitations on Commercial Speech. However, despite the probable attractiveness to some of the Justices of a consistent, bright-line rule for all forms of speech, Justice Thomas has been the only member of the Court to consistently call for the abandonment of the intermediate scrutiny framework. Further, it is not clear whether this case, with complicated mix of speech and conduct, and its indirect targeting of speech by the state, provides an ideal factual background for such a significant change in First Amendment doctrine. As for the FDA, were the Court to announce strict scrutiny for commercial speech in this case, it would face much more difficulty in proving the constitutionality of its off-label prohibitions, but at least would not find its regulatory structure deemed per se unconstitutional, as would be the case with a viewpoint discrimination holding.

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<sup>122</sup> See Tr. at 49:1-7.



Thus, there are several possible outcomes for this case. It appears that Vermont does not stand a particularly good chance of successfully defending its statute against Respondents' claims of First Amendment infringement. However, not all of the negative outcomes against Vermont are equally bad as applied to FDA. FDA faces the greatest threat from a finding that Vermont's § 17 constitutes viewpoint discrimination, given the underlying similarities between the statute and FDA's regulations, and a similar threat from the less likely abandonment of *Central Hudson* in favor of strict scrutiny. Other outcomes, such as a finding that the Vermont statute fails intermediate scrutiny, pose significantly less of a threat to FDA.

## VI. Conclusion

Over the last forty years the Supreme Court has gradually expanded the amount of commercial speech that is protected by the First Amendment. This expansion threatens FDA's ability to regulate claims made by pharmaceutical companies as to off-label uses for their drugs. *IMS Health, Inc. v. Sorrell* represents the latest, and perhaps most serious, threat to FDA's regulatory authority in this area. If the Supreme Court takes *IMS Health* as an opportunity to significantly expand First Amendment protection for commercial speech, FDA's entire regulatory scheme, which was based on a presumption of government's absolute ability to regulate commercial speech, may have to be revisited.